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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FLOOD, MICHELE C

ART UNIT PAPER NUMBER

1655

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

10/689,140

Applicant(s)

BECVAR ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-63 is/are pending in the application.
- 4a) Of the above claim(s) 52-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/6/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, Claims 42-51, in the reply filed on August 23, 2006 is acknowledged.

Claims 52-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 23, 2006.

Claims 42-51 are under examination.

Drawings

Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 recites the limitation "the sample suspected to contain toxic substances" in line 5. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by replacing "the" with a.

Claim 42 recites the limitation "the toxic substances" in line 7. There is a lack of clear antecedent basis for this limitation in the claim. Applicant may overcome the rejection by deleting "the".

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Objections

Claim 44, line 2, is objected to because of the following informalities: Applicant should replace "*Fischer*" with *fishcheri* to place the claim in proper grammatical form. Appropriate correction is required.

With regard to Claim 44, line 9, there is an apparent misspelling. Applicant may overcome the objection by replacing "elusion" with elution.

Doubl Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 42-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 20 of U. S. Patent No. 6,673,563 B1 and claims 1-14, 21-24, 26 and 39 and 41 of U. S. Patent No. 6,017,722 (AA). Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 42-51 are generic to all that is recited in claims 1-10 and 20 of U. S. Patent No. 6,673,563 B1 and claims 1-14, 21-24, 26 and 39-41 of U. S. Patent No. 6,017,722. That is, Claims 42-51 fall entirely within the scope of claims 1-10 and 20 of U. S. Patent No. 6,673,563 B1 and claims 1-14, 21-24, 26 and 39-41 of U. S. Patent No. 6,017,722, or in other words, Claims 42-51 are anticipated by claims 1-10 and 20 of U. S. Patent No. 6,673,563 B1 and claims 1-14, 21-24, 26 and 39-41 of U. S. Patent No. 6,017,722 because the actual process steps,

process materials, process parameters, and resulting functional effect of the process are essentially the same.

Specifically the method of claims 1-10 and 20 of the '563 B1 is a method for identifying the presence of a toxic substance in a sample using a luminescent biological agent, comprising the steps of (a) preparing a luminescent biological agent suitable for use in conjunction with a separation phase matrix; (b) obtaining a test sample suspected to contain a toxic substance; (c) separating said toxic substance from other substances present in said test sample by applying said test sample to said separation phase matrix; and (d) exposing said separated toxic substance to a luminescent biological matrix to identify the presence of said toxic substance by detecting inhibition of luminescence. The '563 B1 method requires the use of a "luminescent biological agent" which is specifically inhibited by an isolated component substance (for example, a toxicant) in a sample (see Column, lines 4-10). The patent method is used in the isolation and identification of the presence of a toxicants in a sample, such as pesticides, through the use of a luminescent biological agent employed together with chromatographic resolution techniques encompassing separating the toxic substances using a separation matrix to provide separated toxic substances, collecting the separated toxic substances by elution from the separation phase matrix into a plurality of serial aliquot volumes; and identifying the presence of the toxic substances harmful to an organism in the aliquot volumes by luminescent inhibition. See Column 2, line 65 bridging Column 4, line 34, of the '563 B1, as well as Column 7, lines 11-26 and Column 20, line 14 bridging Column 22. line 43. In Column 4, lines 34-63, the '563 B1 patent

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clearly defines the term, "luminescent biological agent", as an organism or an extract of an organism, which emits heatless light under appropriate conditions; and, clearly defines each of *Photobacterium leiognathi*, *Photobacterium phosphoreum*, *Vibrio fischeri* (ATCC Acc. No. 7744) or *Vibrio harveyi* (ATCC Acc. No. 33843), a luminescent bacterial, a luminescent fungi, a luminescent firefly extract, a luminescent anthozoan, a luminescent earthworm, a luminescent colenterate extract, a luminescent crustacean, as well as a luminescent cell, and a luciferase gene, as appropriate luminescent systems useful in practice of the patented invention. Figures 1-10 of the '563 B1 patent indicate that the patent method further comprises photography. The Office notes that the specification of the instant application clearly defines the luminescent biological agents as those recited in the Markush groups of the patent Claims 2-3 of '563 B1. The Office further notes that the specification clearly defines a separation phase matrix as either chromatography paper or a thin layer chromatography (TLC) plate which is used for separating toxic substances in a sample, and that the step of separating the toxic substances by applying the test sample to the separation phase matrix is followed by exposing the separated toxic substances (e.g., by spraying a "toxin indicating amount" of a luminescent biological agent to identify the presence of a toxic substances by detecting a zone of luminescence inhibition (see page 13, lines 4 to page 14, lines 1-4, and page 21, lines 13-18 of the instant specification). The test samples can be either in liquid, solid or gaseous form (see Examples 1-11). On page 15, lines 14-23 and page 40, lines 34 to page 41, lines 1-5, in an example for identifying the presence of heavy metals in a sample, the specification clearly defines HPLC as a separation matrix

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wherein, "Successive equal volumes of a heavy metal could be eluted using the HPLC procedure from the HPLC machine and spotted in an array or in a liner fashion of a sheet of (Whatman) chromatograph paper", which is followed by spraying the sheet with a suspension of luminescent bacteria and observing zones of inhibition.

Thus, Claims 42-51 are deemed obvious variant of the limitations of the patented subject matter as per the supporting portions of U. S. Patent No. 6,673,563 B1

Given that U. S. Patent No. 6,017,722 is a substantial duplicate of U. S. Patent No. 6,673,563 B1 and given all of the reasons set forth above, Claims 42-51 are deemed obvious variant of the limitations of the patented subject matter as per the supporting portions of U. S. Patent No. 6,017,722.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
September 19, 2006